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(54) **Cartridge for properly receiving test elements.**

(57) Test elements used in chemical analyzers need to be loaded into a cartridge so that they can be dispensed as required by the analyzer. Problems are often encountered when the cartridge is incorrectly loaded with test elements. Described herein is a cartridge (40A) for receiving test elements (10A) which is sensitive to improper orientation of the test elements as they are being loaded. The cartridge (40A) has a side wall (52A) which is shaped to receive a key (70A) formed on the test element (10A). The arrangement of the side wall (52A) and the key (70A) is asymmetrically located with respect to the center line (16A) of the cartridge (40A) so that test elements (10A) can be inserted only with a proper orientation.

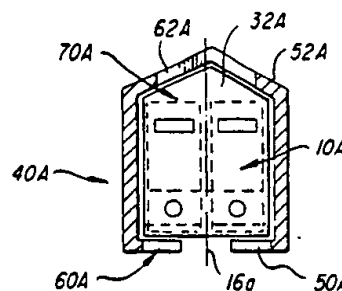


Fig. 5A

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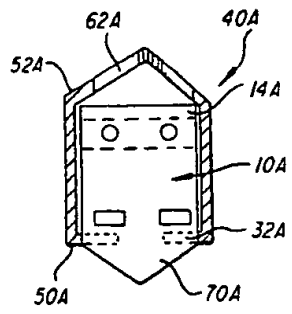


Fig. 5B

CARTRIDGE FOR PROPERLY RECEIVING TEST ELEMENTS

This invention relates to cartridges used to provide test elements to an analyzer to assay sample fluid.

Clinical analyzers, be they large, high-throughput machines, or smaller, lower-throughput machines used in doctor's offices, commonly feature dried test elements for assaying liquids, from cartridges of such test elements. Representative cartridges are shown in U.S. Patent No. Re. 30,595, especially Figure 5. Such cartridges are automatically assembled by machine, so that there is little concern for how the test elements are fed into a stack in the cartridge. That is, their proper orientation is assured by quality control maintained by the automated process. Furthermore, many test elements are symmetric in nature in their top surface, that is, have an aperture for deposit of the sample liquid that is symmetrically located on that top surface. Therefore, such elements are somewhat indifferent as to their orientation. However, those shown in, e.g., U.S. Patent Specification US-A-4273639, are asymmetric since the two liquid deposit apertures are located at one end only, and spaced away from the longitudinal center line of the test element. These test elements, often used for potentiometric measurements, are very sensitive to proper orientation when they are assembled in the cartridge, for readily apparent reasons. Backwards insertion will, of course, locate the liquid deposit apertures at the wrong end. Upside-down insertion is just as unsatisfactory, since in that case the surface to receive the liquid is no longer the top surface, but underneath. (Each of the elements described in the aforesaid two patents is asymmetric about the center plane that extends parallel to the plane of the element.) Nevertheless, as long as automated equipment assembles such test elements into cartridges, the risk of improper orientation is minimized.

Some analyzers, however, have the operator assemble the test elements into a cartridge by hand, prior to placing the cartridge in the analyzer. Particularly, this is desired if the tests to be run are unique for each patient sample. In such a case, it is not possible to prepackage a variety of different test elements in all the possible combinations that a doctor may wish to test. In these instances of hand loading, the risks of improper orientation rise substantially, particularly if one or more of the test elements happens to be asymmetric as described above.

It has been a problem, therefore, to provide a cartridge for test elements that will accept such test elements only in their proper orientation.

These problems are addressed by a cartridge

for test elements, particularly those that are asymmetric, that will accept the test elements only in their proper orientation.

More specifically, in accordance with one aspect of the present invention, there is provided a cartridge for storing and dispensing test elements comprising wall members for confining test elements in a stack, a first opening in one of the wall members for inserting a test element into the stack, a second opening formed in another wall member generally opposite the first opening and through which pusher means can be inserted for ejecting a test element from the stack and through the first opening; characterized in that key means are asymmetrically disposed on one of the wall members and cooperate with mating key means located on each test element in the stack in a matching asymmetric location so that each test element can be inserted into the cartridge in only one orientation.

In accordance with another aspect of the present invention, there is provided a method of orienting one or more test elements to form a stack in a cartridge, the cartridge comprising wall members for confining test elements in a stack, a first opening in one of the wall members for inserting a test element into the stack, a second opening formed in another wall member generally opposite the first opening and through which pusher means can be inserted for ejecting a test element from the stack and through the first opening, the method comprising the steps of:

a) providing key means on one wall member

b) providing mating key means in an asymmetric location on each of the test elements, the key means and mating key means being shaped and located to engage one another, and

c) loading each test element into the cartridge so that the key means and mating key means align with one another to provide the correct orientation of the test elements with respect to the cartridge.

It is an advantageous feature of the invention that a cartridge is provided that will accept a test element to load it in a stack of one or more elements, only if the test element is properly oriented.

It is a related advantageous feature of the invention that a test element improperly oriented cannot be loaded into a cartridge of this invention.

The present invention will now be described by way of example with reference to the accompanying drawings in which:

Figure 1 is a side-by-side plan view of two different kinds of test elements that can be loaded

in a cartridge of this invention;

Figure 2 is an end elevational view of a cartridge constructed in accordance with the invention, the spring-biasing means and test elements having been omitted for clarity;

Figure 3 is a section view taken generally along line II-II of Figure 2, and showing the cartridge fully loaded;

Figure 4 is a fragmentary plan view, partly in section, showing an alternative embodiment of the key and keyway of the invention;

Figures 5A and 5B are section views of an alternate embodiment of the cartridge, taken through the opposed openings in the side walls; and

Figure 6 is a section view similar to that of Figure 5A, but illustrating yet another embodiment.

The invention is described in connection with its preferred embodiments. For example, it is shown with respect to test elements of a preferred type, wherein a keyway is formed on each test element and a key on a wall surface of the cartridge. In addition, the invention is useful with test elements of any type having any chemistry for any assay, and whether the key is on the cartridge or on the test element. (If the key is on the test element, protruding therefrom, then a corresponding keyway is formed in the appropriate wall surface of the cartridge.) In addition, the invention is useful if the test elements are rectangular, as shown, or if they are any other shape such as square.

As shown in Figure 1, there are generally two kinds of test elements 10, 20 useful with the invention. Type 10 is an asymmetric type, having two liquid deposit apertures 12, 12' that are located at one end 14 of the element, either side of the longitudinal center line 16 that extends the length of the test element. Examples of such elements are shown in US-A-4273639 so that further details are unnecessary.

Type 20 is a more symmetric type, for example, a conventional colorimetric type, that has a single liquid-deposit aperture 22 located so as to be centered (at 24) on the longitudinal center line 26 that runs the length of test element 20. However, it is asymmetric insofar as aperture 22 is only located in the top surface 25, and not underneath. The same is true of type 10.

Such test elements have conventionally included, for both types, a notch 30 located at ends 32 of the test element off to the side from center lines 16 and 26. Prior to this invention, these notches have been used exclusively for orienting the parts of the test element only DURING manufacturing, and not thereafter. They had not provided any use in the cartridges which have held them.

In accordance with the invention, a cartridge

40, as shown in Figures 2 and 3, is provided that will accept any of the test elements 10 or 20 only if they are properly oriented. Cartridge 40 preferably comprises opposite end walls 42, 44, and two pairs of opposing side walls 46, 48 and 50, 52, and biasing means 54 for biasing test elements against end wall 42. The biasing means 54 preferably comprises a compression spring 56 and a cylindrical platen 58. Alternatively, not shown, a weighted platen can be used without a spring. Side wall 50 includes an opening 60 shaped to allow test elements to be fed by hand into the cartridge, and to be ejected by the analyzer. In opposite side wall 52 there is an opening 62 that is opposite and generally aligned with opening 60, to allow a pusher blade (not shown) to enter the cartridge to eject a test element out of opening 60. Opening 62 is not large enough to allow a test element to pass through. A ramp 64 is preferably provided on end wall 42 at opening 60 to assist in guiding test elements into the stack against the action of biasing means 54.

Cartridge 40 includes a longitudinal center line 66 (Figure 2) that generally defines a plane in which the longitudinal center lines of test elements E (Figure 3) coincides. Such elements are usually a mixture of types 10 and 20.

To insure the test elements are inserted with the proper orientation, a key 70 is provided protruding from inside surface 72 of wall 52, as best seen in Figure 2. Key 70 is a rib positioned to fit into and mate with notches 30 of test element 10 or 20 if and only if those elements are fed in with end 32 going in first and with the proper (metering) side up. Thus, notches 30 function as keyways. (A notch similar to notch 30 is also preferably formed in platen 58, not shown.) Because the test elements are not square, the key and keyway are not needed to preclude the test elements from being improperly inserted turned 90° from their proper orientation. (However, the key and keyway construction would also be useful to prevent such misorientation if square test elements were used.) As such, therefore, there are four possible insertions of test elements 10 and 20, only one of which can succeed: The permitted one is right-side up with end 32 in first, since in that case notch 30 mates with key 70. The impermissible ones are right-side up with end 32 in last, in which case notch 30 is at the opposite, wrong end for mating with key 70; upside down with end 32 in last so that again notch 30 is at the wrong end; or upside down with end 32 in first, in which case notch 30 is on the opposite, non-mating side of centerline 16. Visual inspection of the cartridge indicates whether each test element has been properly loaded.

Optionally, end wall 42 includes a slot 68 (Figure 2) which allows the interior of the cartridge

40 to be viewed from underneath. The operator or person loading the cartridge can check on the mating of the key and keyway by viewing through this slot.

The actual shapes of key 70 and the notch 30 are shown as being rectangular, but any mating shape is useful, for example, a triangular shape to produce a key with a pointed ridge. It will be readily apparent that notch 30 needs to have an opening that will accommodate the width "w" of the key, as shown in Figure 2, so that even non-congruent shapes 30' can be used if they still mate with the key, for example as shown in Figure 4.

Furthermore, the key or keyway need not be a feature in or on side wall 52. For example, it can be the entire side wall, as shown in Figures 5A and 5B. Parts similar to those previously described bear the same reference numeral, to which the distinguishing suffix "A" has been added. Thus, cartridge 40A receives test elements such as element 10A, through opening 60A in side wall 50A, as in the previous embodiment. Opening 62A is used to push out test elements as they are needed. However, the test elements in this embodiment have a key 70A built onto end 32A, as the entire end feature thereof. Instead of side wall 52A having a notch in one part of it to receive the key, the entire side wall 52A is shaped to receive the key, see Figure 5A. If, however, end 14A were to be put in first, as in Figure 5B, element 10A cannot fit and the operator is alerted to the error. (Alternately, wall 52A can be folded in to form the key, with a notch on element 10A.) Preferably, the point of wall 62A, as well as of the key 70A on the test element, is asymmetrically located with respect to center line 16A, as shown, to prevent the test element from being inserted upside down.

Another example of the cartridge key not being a feature of wall 52 is illustrated in Figure 6, wherein similar parts are shown with the same reference numeral with the letter "B" added. Thus, cartridge 40B receives test elements such as elements 10B through opening 60B in side wall 50B, and a pusher blade extends through opening 62B in side wall 52B to push them out, as before. However, key 70B is now a rib that is part of side wall 46B (or alternatively 48B, not shown), which is an asymmetric location with respect to center line 16B of the elements. Each test element 10B (or 20B, shown in phantom) is provided with a matching notch 30B cut into the appropriate corner of the test element. In such a design, the test element width must be sufficient to accommodate both the notch and the portions providing the testing function.

Claims

1. A cartridge for storing and dispensing test elements comprising wall members (42, 44, 46, 48, 50, 52; 42A, 44A, 46A, 48A, 50A, 52A; 42B, 44B, 46B, 48B, 50B, 52B) for confining test elements (E) in a stack, a first opening (60; 60A; 60B) in one of the wall members (50; 50A; 50B) for inserting a test element (E) into the stack, a second opening (62; 62A; 62B) formed in another wall member (52; 52A; 52B) generally opposite the first opening (60; 60A; 60B) and through which pusher means can be inserted for ejecting a test element from the stack and through the first opening (60; 60A; 60B); characterized in that key means (70; 70A; 70B) are asymmetrically disposed on one of the wall members (52; 52A; 52B) and cooperate with mating key means (30) located on each test element (E) in the stack in a matching asymmetric location so that each test element (E) can be inserted into the cartridge in only one orientation.

2. A cartridge according to claim 1, wherein the key means (70; 70A; 70B) protrudes from the wall member (52; 52A; 52B) having the second opening (62; 62A; 62B).

3. A cartridge according to claim 1 or 2, wherein the key means (70; 70A; 70B) extends at least the height of the stack along any one of the side wall members (46, 48, 50, 52; 46A, 48A, 50A, 52A; 46B, 48B, 50B, 52B).

4. A method of orienting one or more test elements (E) to form a stack in a cartridge, the cartridge comprising wall members (42, 44, 46, 48, 50, 52; 42A, 44A, 46A, 48A, 50A, 52A; 42B, 44B, 46B, 48B, 50B, 52B) for confining test elements (E) in a stack, a first opening (60; 60A; 60B) in one of the wall members (50; 50A; 50B) for inserting a test element (E) into the stack, a second opening (62; 62A; 62B) formed in another wall member (52; 52A; 52B) generally opposite the first opening (60; 60A; 60B) and through which pusher means can be inserted for ejecting a test element from the stack and through the first opening (60; 60A; 60B), the method comprising the steps of:

a) providing key means (70; 70A; 70B) on one wall member (52; 52A; 52B)

b) providing mating key means (30) in an asymmetric location on each of the test elements, the key means (70; 70A; 70B) and mating key means (30) being shaped and located to engage one another, and

c) loading each test element (E) into the cartridge so that the key means (70; 70A; 70B) and mating key means (30) align with one another to provide the correct orientation of the test elements with respect to the cartridge.

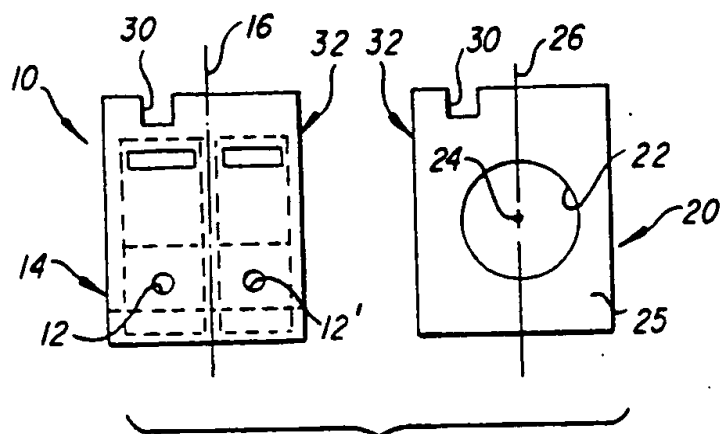


Fig. 1

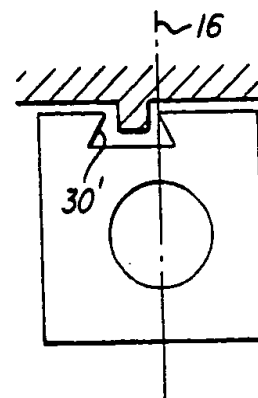


Fig. 4

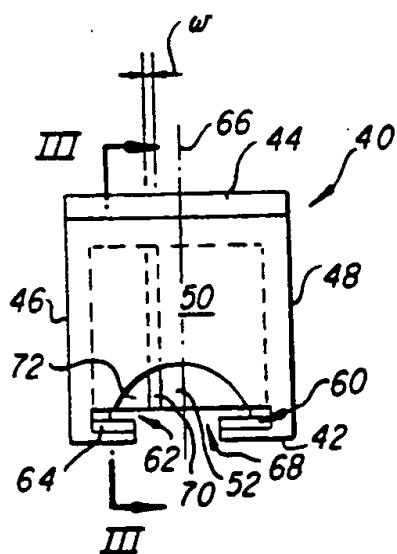


Fig. 2

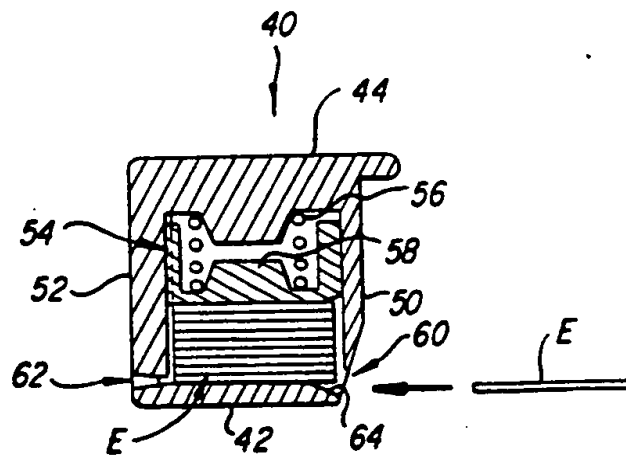


Fig. 3

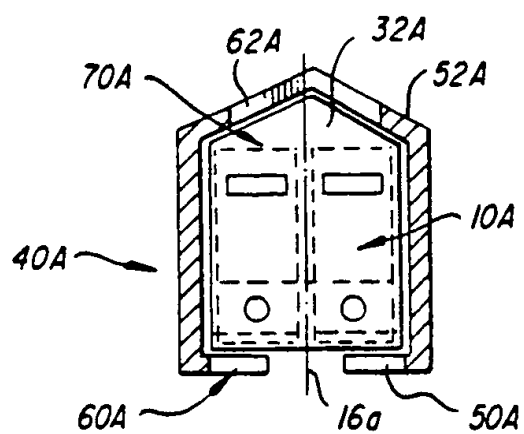


Fig. 5A

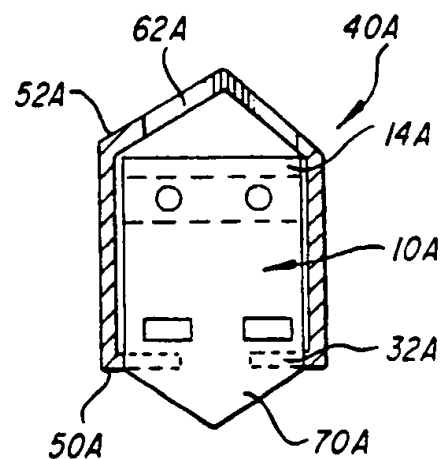


Fig. 5B

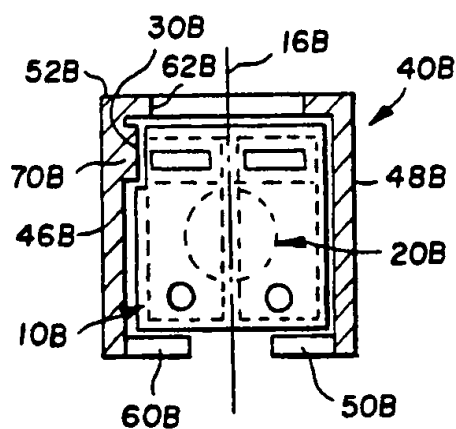


Fig. 6



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54 Cartridge for properly receiving test elements.

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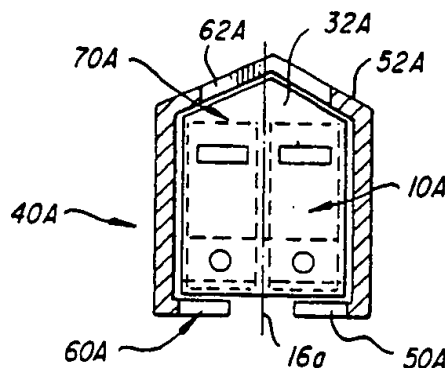


Fig. 5A

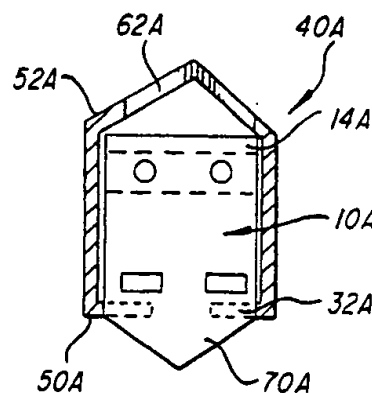


Fig. 5B

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European
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EUROPEAN SEARCH REPORT

Application Number

EP 90 30 0067

DOCUMENTS CONSIDERED TO BE RELEVANT					
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)		
X	US-A-4 159 875 (ABBOTT LABORATORIES) * Figure 3; column 2, line 66 - column 3, line 5; figure 7 *	1,3,4	B 01 L 9/06 G 01 N 35/00		
A	---	2			
Y	US-A-4 118 280 (CHARLES et al.) * Column 3, line 65 - column 4, line 18; column 10, lines 4-36 *	1,4			
Y	EP-A-0 006 031 (EASTMAN KODAK) * Page 4, line 25 - page 5, line 34 *	1,4			
			TECHNICAL FIELDS SEARCHED (Int. Cl.5)		
			B 01 L 3/00 B 01 L 9/00 B 01 L 11/00 G 02 B 21/00 B 65 D 83/00 G 01 N 35/00		
The present search report has been drawn up for all claims					
Place of search The Hague		Date of completion of search 15 January 91	Examiner BINDON C.A.		
<table border="0"><tr><td>CATEGORY OF CITED DOCUMENTS X: particularly relevant if taken alone Y: particularly relevant if combined with another document of the same category A: technological background O: non-written disclosure P: intermediate document T: theory or principle underlying the invention</td><td>E: earlier patent document, but published on, or after the filing date D: document cited in the application L: document cited for other reasons &: member of the same patent family, corresponding document</td></tr></table>				CATEGORY OF CITED DOCUMENTS X: particularly relevant if taken alone Y: particularly relevant if combined with another document of the same category A: technological background O: non-written disclosure P: intermediate document T: theory or principle underlying the invention	E: earlier patent document, but published on, or after the filing date D: document cited in the application L: document cited for other reasons &: member of the same patent family, corresponding document
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